Docket No.: NY-MSI 203-US
(PATENT)

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Dated: 9/20/06 Signature: Fani Malikouzakis
(Fani Malikouzakis)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Edward F. Ikeguchi et al.

Application No.: 10/667,848 Confirmation No.: 1385

Filed: September 22, 2003 Art Unit: N/A

For: SYSTEM AND METHOD FOR CONTINUOUS DATA ANALYSIS OF AN ONGOING CLINICAL TRIAL Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Copies of the references on the PTO/SB/08 are not provided.

A concise explanation of relevance of the items listed on form PTO/SB/08 is given for each listed item.

U.S. Patent No. 6,829,623 to Tsuchida et al. (Tsuchida) describes a system for maintaining and reorganizing a plurality of database storage units without interrupting ongoing access to the storage units. The storage units maintain substantially identical data, such that while one storage unit is being updated, the other can be accessed by users. The storage units are then synchronized. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Tsuchida, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Tsuchida does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 5,687,722 to Tien et al. (Tien) describes a method for enhancing the measurement of physiological signals in the presence of noise. The method involves using light signals to derive a pulse oximetry signal. Data from light sources is used to determine a ratio value, which is then statistically analyzed to estimate the correct ratio value. This value is then processed to determine the physiological measurement such as oxygen saturation within a patient, carbon monoxide levels in the blood, etc. Tien describes a system for taking such measurements. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Tien, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as

required by the claims of the present invention. Accordingly, Tien does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,820,235 and U.S. Published Patent Application No. 2005/0149852 to Bleicher et al. (Bleicher) describe a system and method for collecting and managing clinical trial data. A graphical user interface is constructed from meta-information describing a clinical trial. Generated data entry forms allow users to easily enter patient information. An authentication procedure is required to gain access to the system. That is, Bleicher describes gathering, storing and organization of the trial data. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Bleicher, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Bleicher does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent Nos. 6,575,901 and 6,572,556 to Stoycos et al. (Stoycos) describe a multi-user system for real-time data access during cardiology procedures. The Stoycos system includes an interactive computer network which allows data from a cardiology procedure and any data updates to be distributed to a plurality of devices at a plurality of locations, for real-time viewing. The Stoycos system allows multiple clinicians that are in different areas of a lab to simultaneously interact with, manipulate and document observations on the clinical data in order to diagnose and treat heart conditions. The annotations are replicated and distributed to other locations through a central publisher. That is, Stoycos describes monitoring data during a cardiac catheterization procedure

while the procedure is being conducted in a cardiac catheterization lab. The clinicians know who the patient is and view the data as the patient is undergoing the procedure. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Stoycos, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Stoycos does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,922,654 to Krebs et al. (Krebs) describes a method to detect when a radioactivity measurement exceeds a predetermined limiting value. Single measurements of radioactivity are performed, and a probability is calculated after each measurement. The procedure continues until a calculated probability is smaller than or equal to the limiting value. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Krebs, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Krebs does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,368,284 to Bardy (the '284 patent) describes an automated system for diagnosing and monitoring the onset, progression, regression and status quo of myocardial ischemia. Measures of patient cardiovascular information are recorded on a

regular periodic basis. A comparison of recorded measures determines patient status change, which is then compared to quantified indicator thresholds to detect the principal manifestations of myocardial ischemia. The indicator threshold corresponds to a measure of a pathophysiology which is indicative of myocardial ischemia. That is, the '284 patent describes diagnosing and monitoring myocardial ischemia. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. The '284 patent, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, the '284 patent does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,398,728 to Bardy (the '728 patent) describes an automated system for diagnosing and monitoring the onset, progression, regression and status quo of respiratory insufficiency. Measures of patient cardiopulmonary information are recorded on a regular periodic basis. A comparison of recorded measures determines patient status change, which is then compared to quantified indicator thresholds to detect the principal manifestations of respiratory insufficiency. The indicator threshold corresponds to a measure of a pathophysiology which is indicative of respiratory insufficiency. That is, the '728 patent describes diagnosing and monitoring respiratory insufficiency. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. The '728 patent, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention.

Accordingly, the '728 patent does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,908,437 to Bardy (the '437 patent) describes a system for diagnosing and monitoring the onset, progression, regression and status quo of congestive heart failure. Measures of patient cardiovascular information are recorded on a regular periodic basis. A comparison of recorded measures determines patient status change, which is then compared to quantified indicator thresholds to detect the principal manifestations of congestive heart failure. The indicator threshold corresponds to a measure of a pathophysiology which is indicative of congestive heart failure. That is, the '437 patent describes diagnosing and monitoring congestive heart failure. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. The '437 patent, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, the '437 patent does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,411,840 to Bardy (the '840 patent) describes an automated system for diagnosing and monitoring the outcomes of atrial fibrillation. Measures of patient cardiovascular information are recorded on a regular periodic basis. A comparison of recorded measures determines patient status change, which is then compared to quantified indicator thresholds to detect the principal manifestations of atrial fibrillation. The indicator threshold corresponds to a measure of a pathophysiology resulting from atrial fibrillation. That is, the '840 patent describes diagnosing and

monitoring atrial fibrillation. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. The '840 patent, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, the '840 patent does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 5,757, 664 to Rogers et al. (Rogers) describes a system and apparatus for monitoring a fluid storage and dispensing system. Data that is continuously collected from the apparatus is statistically analyzed to determine operational information about the system. A warning is delivered if there is a leak in the system. That is, Rogers describes monitoring liquid storage containers or tanks to determine if there is a leak. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Rogers, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Rogers does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,834,256 to House et al. (House) describes a system for determining the reliability and time remaining before failure of electric motor systems. Data relating to the motor system is continuously uploaded to a database and a statistical analysis of the data is performed to determine the amount of remaining motor life.

Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. House, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, House does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,904,434 to Wallach et al. (Wallach) describes a system of providing real time access to clinical trial subject enrollment data pertaining to various parameters. Investigators can enter clinical trial data using web-based forms, and can view tabulated and chart information pertaining to the data. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Wallach, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Wallach does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,832,110 to Sohmer et al. (Sohmer) describes a method of analyzing EEG and EP data in order to differentiate between ongoing and evoked neuro-electric activity of the brain of a subject. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Sohmer, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into

groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Sohmer does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

Patent 5,924,073 to Tyuluman et al. (Tyuluman) describes a system for assessing physician performance using statistical analysis. A database stores data related to physician-patient contact. An evaluator coupled to the database uses multivariate techniques to identify outliers and establish a standard of care. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Tyuluman, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Tyuluman does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Patent No. 6,418,334 to Unger et al. (Unger) describes a system for logging and analyzing performance data for a medical diagnostic imaging system. Raw performance data is acquired, then processed in real time to produce characteristic data summarizing the raw performance data. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Unger, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the

claims of the present invention. Accordingly, Unger does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2004/0078228 to Fitzgerald et al. (Fitzgerald) describes a system used to monitor healthcare financial and clinical encounter related information. The system monitors by detecting statistically significant patterns in the data, such as those relevant to fraud, disease outbreaks and cost reduction opportunities. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Fitzgerald, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Fitzgerald does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2004/0133450 to Foureaux et al. (Foureaux) describes a control system and method for performing clinical trials whereby the number of patients needed for screening examinations is determined The control mechanism books patient appointments or excludes patients based upon predetermined enrollment targets. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Foureaux, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of

the present invention. Accordingly, Foureaux does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2005/0038692 to Kane et al. (Kane) describes a system for matching patients with appropriate clinical trials based upon predetermined parameters. The system trains raters to apply similar criteria when determining whether a subject is qualified for a clinical trial. This results in standardized, centralized ratings. That is, Kane describes selecting patients for participation in a trial Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Kane, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Kane does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2005/0149869 to Kehr et al. (Kehr) describes a system for monitoring, prompting and recording the adherence to a trial protocol by the participants, encouraging adherence to trial protocol by trial participants, and comparing the gathered data to predetermined desired benchmarks. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Kehr, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Kehr does

not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2005/0010451 to Marks et al. (Marks) describes a clinical trial data collection and management system that also integrates with training functions for end users of the system. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Marks, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Marks does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2004/0148195 to Kalies (Kalies) describes a method for gathering, processing, storing and reporting pharmacy data to a repository that may be queried for desired data. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Kalies, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Kalies does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2004/0243439 to Huggard et al. (Huggard) describes an automatic data collection, storage and reporting system for clinical data that eliminates the need for manual procedures. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Huggard, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Huggard does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

U.S. Published Patent Application No. 2004/0243440 to Narimatsu et al. (Narimatsu) describes an information system for gathering medical information from a plurality of medical measurement devices and outputting data to statistical data sets. Whereas, the present invention teaches and suggests a system and method for continuously performing statistical analysis on clinical data of an ongoing clinical trial. Narimatsu, however, does not teach or suggest continuously analyzing clinical data from an ongoing clinical trial, segregating data into groups during blinded trials, aggregating clinical data into groups without revealing the composition of the groups and analyzing clinical data for statistical significance, as required by the claims of the present invention. Accordingly, Narimatsu does not teach or suggest "performing a statistical analysis on the accessed trial database" and "determining whether the result of the statistical analysis exceeds a predetermined threshold value" as called for in representative method claim 1.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an

admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0624, under Order No. NY-MSI 203-US (10406788).

Dated: 9/20/07

Respectfully submitted,

By _____

C. Andrew Im
Registration No.: 40,657
FULBRIGHT & JAWORSKI L.L.P.
666 Fifth Avenue
New York, New York 10103
(212) 318-3000
(212) 318-3400 (Fax)
Attorney for Applicant

Application No. (if known): 10/667,848 Attorney Docket No.: NY-MSI 203-US

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IDS (Citation) by Applicant (2 pages)